UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

MEMORANDUM

DATE: April 2, 2013

SUBJECT: Efficacy Review for Sterilex Ultra Disinfectant Cleaner Solution 1
EPA Reg. No. 63761-8
DP Barcode: D407789

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APPLICANT: Sterilex Corporation
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FORMULATION FROM LABEL:

Active Ingredient(s)	% by wt.
n-Alkyl (C_{12} 68%, C_{14} 32%) dimethylethylbenzyl ammonium chloride	3.00%
n-Alkyl (C_{14} 60%, C_{16} 30%, C_{12} 5%, C_{18} 5%) dimethylbenzyl ammonium chloride	3.00%
Hydrogen peroxide	6.30%
Inert Ingredients	87.70%
Total	100.00%

I BACKGROUND

The product, Sterilex Ultra Disinfecting Cleaner Solution 1 (EPA Reg. No. 63761-8), is an EPA approved, one-step disinfectant (bactericide, virucide, Fungistat/mildewstat) for use on hard, non-porous surfaces in hospitals, homes, medical, dental offices, nursing homes, healthcare facilities, ultrasonic baths, food processing facilities, meat and poultry plants, wineries, breweries, farm premises, hatcheries, refrigerated trucks, kennels, pet animal quarters, zoos, pet shops, animal laboratories, veterinary facilities, and other commercial facilities. The proposed label states that the product is effective in the presence of a 5% organic soil load in 400ppm AOAC hard water. The applicant has requested to amend the registration of this product to add new claims for effectiveness as a non-food contact sanitizer against *Enterobacter aerogenes* (ATCC 13048). Efficacy studies were conducted at ATS Labs located at 1285 Corporate Center Drive, Suite 110, Eagan, MN, 55121.

This data package contained a letter from the applicant to the Agency (dated, December 4, 2012), EPA Form 8570-35 (Data Matrix), Application for Pesticide Amendment Form), Certification With Respect To Data (Form?), proposed product label, transmittal document, and one study (MRID 49010901) with Statement of No Data Confidentiality Claims.

II. USE DIRECTIONS

The product, Sterilex Ultra Disinfectant Cleaner is designed for disinfecting and sanitizing hard, non-porous surfaces. The proposed label indicates that the product may be used as a disinfectant on surfaces such as, floors, walls, countertops, stovetops, sinks, appliances, refrigerators, non-porous cutting boards and chopping blocks, food processing equipment and food processing equipment. The product is part of a two part system that must be used in conjunction with Sterilex Ultra Activator Solution to support the public health claims. The product is recommended for use on the following types of surfaces: metal, stainless steel, glazed porcelain, glazed ceramic, sealed stone, hard fiberglass, plastic (including polystyrene, and polypropylene), painted wood, Formica®, and vinyl. Directions on the proposed label provide the following information regarding use of the product as a disinfectant:

> Sterilex Ultra Disinfectant Cleaner Solution 1, when mixed with Sterilex Ultra Activator Solution, is a one-step hospital-use disinfectant at 12.8 fl. oz. (each, Solution 1 & Solution 2) per gallon of water (1:1:10)....in the presence of 400 ppm hard water plus 5% organic serum.

Directions on the proposed label state the following information regarding the use of the product as a **sanitizer:**

Add 2 fl. oz. [59mL] of Sterilex Ultra Disinfectant Cleaner Solution1 and 2 fl. oz.[59mL] of Sterilex Ultra Activator Solution to 1 gallon of water (or equivalent use dilution) to sanitize hard, non-porous surfaces. Apply sanitizer use solution to pre-cleaned, hard, non-porous surfaces with a cloth, mop, sponge, sprayer, foaming or by immersion. For sprayer applications, use a coarse pump or trigger sprayer. Spray 6-9 inches from surface and rub with brush sponge or cloth.

III. AGENCY STANDARDS

Sanitizer Test (for inanimate, non-food contact surfaces): The effectiveness of sanitizers for non-food contact surfaces must be supported by data that show that the product will substantially reduce the numbers of test bacteria on a treated surface over those on an untreated control surface. The test surface(s) should represent the type(s) of surfaces recommended for treatment on the label, i.e., porous or non-porous. Products that are represented as "one-step sanitizers" should be tested with an appropriate organic soil load, such as 5 percent serum. Tests should be performed with each of 3 product samples, representing 3 different product lots, one of which is at least 60 days old against *Staphylococcus aureus* (ATCC 6538) and either *Klebsiella pneumoniae* (aberrant, ATCC 4352) or *Enterobacter aerogenes* (ATCC 13048 or 15038). Results must show a bacterial reduction of at least 99.9% (percent) over the parallel control within 5 minutes.

Supplemental Claims: An antimicrobial agent identified as a "one-step" disinfectant or as effective in the presence of organic soil must be tested for efficacy with an appropriate organic soil load, such as 5 percent serum. On a product label, the hard water tolerance level may differ with the level of antimicrobial activity (e.g., sanitizer vs. disinfectant) claimed. To establish efficacy in hard water, all microorganisms (i.e., bacteria, fungi, and viruses) claimed to be controlled must be tested by the appropriate Recommended Method at the same hard water tolerance level.

IV. Brief Description of the Data

1. MRID 49010901: "Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces (Dilutable). Test Organisms: *Enterobacter aerogenes* (ATCC 13048) and *Staphylococcus aureus* (ATCC 6538)" for Sterilex Ultra Disinfectant Cleaner Solution 1, by Jill Ruhme. Study conducted at ATS Labs. Study completion date – December 27, 2012. Project Number A12359.

This study was conducted against *Enterobacter aerogenes* (ATCC 13048) and *Staphylococcus aureus* (ATCC 6538). Three lots (Lots BT26439 and BT26405 (both ≥60 days old), Lot BT26902 and BT27002 and Lot BT27030 and Lot BT27026) of the product, Sterilex Ultra Disinfectant Cleaner Solution 1, were tested according to the ASTM Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces, July 2003, (ATS Labs protocol # SLX01110311.NFS). The product was prepared using 1.56 mL Sterilex Ultra Disinfectant + 1.56 mL Serilex Activator Solution + 100 mL of sterilized tap water. No Fetal bovine serum was added to the inoculum. From a stock slant, an initial tube of culture broth was inoculated. A minimum of 3 daily transfers of the culture media was performed on consecutive days prior to testing. A 48-54 hour broth culture was vortex mixed and allowed to settle for approx. 15 minutes. The upper 2/3rd's of the culture was removed and transferred to a sterile vessel for use in testing. Sterile carriers were inoculated with 0.02mL of culture using a calibrated pipettor spreading the inoculum to the edges of the carrier. Inoculated carriers were dried for 20 minutes at 35-37°C and a relative humidity of 40% with the Petri dish lids slightly ajar. Following drying, each of 5 carriers and 3 controls were

transferred to individual sterile jars using sterile forceps. Using staggered intervals, 5.0 mL of prepared test substance was transferred to each jar. Remaining jars were treated in the same manner. Carriers were allowed to expose at room temperature (20°C) for 3 minutes. Following exposure, 20 mL of neutralizer was transferred to the jars using identical staggered intervals. The carriers were vortex-mixed. Within 30 minutes of neutralization, duplicate 1.00mL aliquots of the neutralized solution (100) and duplicate 1.00 mL aliquots of a ten-fold dilution (10-1) were plated onto the recovery agar plate medium for both organisms. *S. aureus* plates were incubated at 35-37°C for 48 ± 4 hours and *E. aerogenes* plates were incubated for 48 ± 4 hours at 25-30°C. Following incubation, the subcultures were visually enumerated. Controls included those for purity, sterility, neutralization confirmation, and carrier population.

V. RESULTS

MRID Number	Organism	Lot No.	Average Log_{10} CFU/carrier	Geometric Mean CFU/carrier	Percent Reduction
3-Minute Exposure Time in Sterilized Tap Water					
49010901	*Enterobacter aerogenes* (ATCC 13048)	BT26439 BT26902 BT27030	<1.40	$<2.51 \times 10^{-1}$	>99.9
49010901	*Staphylococcus aureus* (ATCC 6538)	BT26439 BT26902 BT27030	<1.40	$<2.51 \times 10^{-1}$	>99.9

VI. CONCLUSIONS

1.) The submitted efficacy data (MRID No. 49010901) **supports** the use of the product, Sterilex Ultra Disinfecting Cleaner Solution 1 (when used in conjunction with the Sterilex Activator Solution) with tap water, as a non-food contact sanitizer against the following organisms on hard, non-porous surfaces for a 3 minute contact time:

Enterobacter aerogenes (ATCC 13048) MRID 49010901
Staphylococcus aureus (ATCC 6538) MRID 49010901

VII. RECOMMENDATIONS

1. The proposed label claims that the product, Sterilex Ultra Disinfecting Cleaner Solution 1 when used in conjunction with the Sterilex Activator Solution, is an effective non-food contact sanitizer against the following microorganisms on hard, non-porous surfaces for a 10 minute contact time in the presence of a 5% organic soil load:

Enterobacter aerogenes (ATCC 13048)
Staphylococcus aureus (ATCC 6538)

These claims are acceptable as they are supported by the submitted data.

2. **The following revisions must be made to the proposed label:**

   1. All **"cross-contamination"** language is to be removed from the proposed Sanitization label language on pages 7 thru 14 of proposed label. These statements can be misleading on pesticide labels and imply a false claim or suggest a certain level of safety from contamination.

   2. On page 4 of the proposed label, please replace the phrase, "eliminates 99.9% of the following bacteria" with **"significantly reduces by 99.9%", or "reduces the following bacteria by 99.9%".**